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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,748	08/30/2001	Hideya Takeo	Q65987	7384

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EXAMINER	
KRONENTHAL, CRAIG W	

ART UNIT	PAPER NUMBER
2623	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,748	TAKEO ET AL.	
	Examiner	Art Unit	
	Craig W Kronenthal	2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on 30 August 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/30/01.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 4, 5, 6, 7, and 10/7 are rejected under 35 U.S.C. 102(b) as being anticipated by Giger et al. (P.N. 5,133,020). (hereinafter Giger)

Regarding Claim 1: Giger discloses a method of detecting suspected anomalous shadows, comprising the steps of:

- Obtaining radiation-image data (210 and 220) representing a radiation image obtained of a target subject by an image obtaining means (10 and 1101, col. 9 lines 20-22)
- Detecting (20), based on said obtained radiation image data (210 and 220), the suspected anomalous shadows contained within said radiation image by performing an anomalous shadow detection process utilizing a predetermined detection parameter, further comprising the steps of:
    - Obtaining phantom-image data (330) representing a radiation image obtained by said radiation image obtaining means of a standard phantom having a shadow pattern formed of a plurality of evaluative models each of which corresponds to a different detection level.

Giger's gray-level histograms (430 and 440) are equivalent to phantom image data. The histograms consist of pixels at different gray levels. Therefore a cluster of similar gray levels amongst other gray levels represent shadow patterns. The threshold value is then chosen for detection depending on the range of gray levels of each cluster.

- Outputting said obtained phantom image data by use of an output means

  The output means is represented by the arrows pointing from the histograms (430 and 440) to the N Threshold Images steps (450 and 460). (see Figure 6)

- Setting as the value of the detection parameter a threshold value obtained by performing an image quality evaluation based on the phantom-image data outputted by the output means (col. 6 lines 39-44).

  Giger actually does this process N times for each of N threshold values. The image quality evaluation of the phantom-image used to determine the threshold value is the process of choosing "a level corresponding to a specific percentage of the area under the gray-level histogram" where the gray-level histogram is the outputted phantom-image as explained above.

Regarding Claim 2: Giger discloses the method defined in claim 1, wherein the target subject is a breast (col. 2 lines 41-48). Here the breasts are listed as just one of a

number of different target subject, but is should also be noted that the breasts were used in examples throughout the specification.

Regarding Claim 3: Giger discloses a system for detecting suspected anomalous shadows, comprising:

- Image obtaining means for obtaining a radiation image of a target subject (10 and 1101, col. 9 lines 20-22)
- Radiation-image data obtaining means for obtaining radiation-image data representing the radiation image obtained by said image obtaining means of the target subject (210 and 220)
- An anomalous shadow detecting means for detecting (20), based on the radiation-image data obtained by the radiation image data obtaining means (210 and 220), suspected anomalous shadows contained within the radiation image by performing an anomalous shadow detection process utilizing a predetermined detection parameter

  Giger uses gray-level thresholding on a radiation image to extract suspected lesions, which one skilled in the art of radiation imaging understands to be represented by shadow (col. 5 line 67- col. 6 line 2).

  Giger also explains how a thresholding value, which acts as a predetermined detection parameter, is used for detecting the shadows in a gray-level histogram (col. 6 lines 34-50).

- Said anomalous shadow detecting means determines, based on a phantom-image data (330) representing a standard phantom-image having at least one type of anomalous shadow pattern formed of a plurality of evaluative models each of which corresponds to a different detection capability level, a threshold value facilitating the detection and obtainment of an evaluative model corresponding to a desired detection capability level

  The phantom-image data is represented by Giger's gray-level histogram. It is well known to one skilled in the art of radiation imaging that gray-level histograms show anomalous shadow patterns when a tumor, lesion, microcalcification, etc. are present. Such a shadow pattern is represented by a plurality of gray pixels having a different contrast than the surrounding background pixels. As explained above regarding this claim, Giger uses a threshold value as a predetermined detection parameter. Furthermore, Giger's threshold value facilitates the detection and obtainment of an evaluative model corresponding to a desired detection capability level since multiple threshold values are determined (col. 6 lines 34-50) allowing for a desired threshold image to be chosen for detection (140, col. 7 lines 45-49).

- And automatically sets the value of the detection parameter based on said threshold value (col. 2 lines 33-36)

  Giger claims his system and method, which includes the process of thresholding, to be automatic. Although Giger does not use the term

detection parameter he does use the threshold value in the same manner as the detection parameter as explained above.

Regarding Claim 4: Giger discloses the system as defined in claim 3 wherein at least one of the patterns of anomalous shadows contained in the standard phantom is the pattern of the shadows of tumors (col. 2 lines 33-36). Giger includes the detection of all parenchymal distortions in his method and system of detection. A tumor is by definition a parenchymal distortion. Therefore, its shadow pattern would be detected.

Regarding Claim 5: Giger discloses the system as defined in claim 3 wherein at least one of the patterns of anomalous shadows contained in the standard phantom is the pattern of the shadows of microcalcifications (col. 2 lines 33-36). Giger includes the detection of all parenchymal distortions in his method and system of detection. A microcalcification is by definition a parenchymal distortion. Therefore, its shadow pattern would be detected.

Regarding Claim 6: Giger discloses the system fore detecting suspected anomalous shadows as defined in claim 3, wherein said suspected anomalous shadow detection process comprises an iris filtering process for detecting tumors, or a morphology filtering process for detecting microcalcifications (col. 12 lines 26-28). The morphological filtering is done as part of the detection process to more accurately determine the area of the lesion, microcalcification, tumor, etc.

Regarding Claim 7: Giger discloses a system for detecting suspected anomalous shadows, comprising:

- Image obtaining means for obtaining a radiation image of a target subject (10 and 1101, col. 9 lines 20-22)
- Radiation-image data obtaining means for obtaining radiation data representing the radiation image obtained by said image obtaining means of the target subject (210 and 220)
- An anomalous shadow detecting means for detecting (20), based on the radiation-image data obtained by the radiation image data obtaining means (210 and 220), suspected anomalous shadows contained within the radiation image by performing an anomalous shadow detection process utilizing a predetermined detection parameter further comprising:

Giger uses gray-level thresholding on a radiation image to extract suspected lesions, which one skilled in the art of radiation imaging understands to be represented by shadow (col. 5 line 67- col. 6 line 2). Giger also explains how a thresholding value, which acts as a predetermined detection parameter, is used for detecting the shadows in a gray-level histogram (col. 6 lines 34-50).

- A parameter setting means for automatically setting, based on the radiation-image data of a predetermined target subject that has been obtained by the radiation-image data obtaining means from a radiation

image obtained thereof by the image obtaining means, the value of the detection parameter. (col. 2 lines 33-36)

Giger claims his system and method, which includes the process of thresholding, to be automatic. Although Giger does not use the term detection parameter he does use the threshold value in the same manner as the detection parameter as explained above. The threshold value is based on the area under the gray-level histogram corresponding to a target subject (col. 6 lines 39-44).

Regarding Claim 10 (as dependent on claim 7): Giger discloses a system as defined in claim 7, wherein the predetermined target subject is a standard phantom having a pattern of anomalous shadows formed of a plurality of evaluative models each of which corresponds to a different detection capability level. Each of Giger's gray-level histograms (430 and 440) are equivalent to a phantom of a target subject, in this case the left and right breasts. The histograms consist of pixels at different gray levels. It is well known to those in the art of radiation imaging that a cluster of similar gray levels amongst other gray levels represent shadow patterns. The threshold value is then chosen for detection depending on the range of gray levels of each cluster.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 8, 9, 10/8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Norimatsu (P.N. 6,415,053).

Regarding Claim 8: Giger discloses a system for detecting suspected anomalous shadows as defined in claim 7, but does not disclose the correction of the detection parameter for granularity. However, Norimatsu does disclose the parameter setting means that computes a granularity correction value, based on the granularity of the radiation-image data of the predetermined target subject, and sets the value for the detection parameter based on said granularity correction value (col. 29 lines 35-41). Norimatsu's key correcting subsection 228 is responsible for calculating a granularity correction amount and supplying the correction amount to a parameter coordinating subsection. It would be obvious to one skilled in the art of radiation imaging to modify Giger with the teachings of Norimatsu so that Giger's system includes a granularity correction subsection 228 and a parameter coordinating subsection for setting the correction amount to the predetermined detection parameter. One would be motivated to make this modification because correcting the granularity of an image would produce a smoother image to aid in a more accurate detection process.

Regarding Claim 9: Giger discloses a system for detecting suspected anomalous shadows as defined in claim 7, but does not disclose the correction of the detection parameter for contrast. However, Norimatsu does disclose the parameter setting

means that computes a contrast correction value, based on the granularity of the radiation-image data of the predetermined target subject, and sets the value for the detection parameter based on said granularity correction value (col. 29 lines 35-41). Norimatsu's key correcting subsection 228 is also responsible for calculating a contrast correction amount and supplying the correction amount to a parameter coordinating subsection. It would be obvious to one skilled in the art of radiation imaging to modify Giger with the teachings of Norimatsu so that Giger's system includes a contrast correction subsection 228 and a parameter coordinating subsection for setting the correction amount to the predetermined detection parameter. One would be motivated to make this modification because correcting the contrast of an image would produce a sharper image to aid in a more accurate detection process.

Regarding Claim 10 (as dependent on claim 8): Giger as modified by Norimatsu, discloses a system as defined in claim 8. Giger further discloses that the predetermined target subject is a standard phantom having a pattern of anomalous shadows formed of a plurality of evaluative models each of which corresponds to a different detection capability level. Each of Giger's gray-level histograms (430 and 440) are equivalent to a phantom of a target subject, in this case the left and right breasts. The histograms consist of pixels at different gray levels. It is well known to those in the art of radiation imaging that a cluster of similar gray levels amongst other gray levels represent shadow patterns. The threshold value is then chosen for detection depending on the range of gray levels of each cluster.

Regarding Claim 11: Giger as modified by Norimatsu, discloses a system as defined in claim 9. Giger further discloses that the predetermined target subject is a standard phantom having a pattern of anomalous shadows formed of a plurality of evaluative models each of which corresponds to a different detection capability level. Each of Giger's gray-level histograms (430 and 440) are equivalent to a phantom of a target subject, in this case the left and right breasts. The histograms consist of pixels at different gray levels. Therefore a cluster of similar gray levels amongst other gray levels represent shadow patterns. The threshold value is then chosen for detection depending on the range of gray levels of each cluster.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Takeo (Patent Application US 2001/0019623 A1) is cited for teaching an anomalous shadow detection system.
- Nakajima (P.N. 5,583,346) is cited for teaching a method for detecting prospective abnormal patterns including the use of experimental threshold values.
- Nakajima et al. (P.N. 5,761,334) is cited for teaching a computer aided diagnosis of medical images having abnormal patterns, specifically the detection method invloved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig W Kronenthal whose telephone number is (703) 305-8696. The examiner can normally be reached on 8:00 am - 5:00 pm / Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 306-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CWK
09/03/04

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